To address this judicial confusion, this bill simply clarifies that a chapter 13 debtor who is subject to section 1325(b)(3) of the Bankruptcy Code, may make charitable contributions or tithe to the same extent determined in accordance with Bankruptcy Code section 1325(b)(2)(A)(ii).

S. 4044 is a bipartisan measure that makes good sense. Donations are used by religious or charitable organizations to fund valuable services to society which serve the common good. This principle, for example, is recognized in the Internal Revenue Code's provisions concerning the deductibility of certain charitable contributions. Individuals who, for religious or other reasons, wish to donate to such organizations, even if they are in bankruptcy themselves, should not be deprived of this right.

I urge my colleagues to support this bill.

Mr. Speaker, I reserve the balance of my time.

Mr. CONYERS. Mr. Speaker, I yield myself as much time as I may consume. And I am pleased to rise in support of the Religious Liberty and Charitable Donations Act of 2006.

This, ladies and gentlemen, is a continuation of an effort we began in 1997 when Congress responded to cases holding that pre-petition tithes and other charitable contributions could be deemed to be fraudulent transfers, and that the trustee could recoup these tithes from the religious institutions receiving the donations.

We all agreed that this was a clearly perverse result, and to clarify the law we passed the measure, Religious Liberty and Charitable Donation Protection Act of 1998.

Then a funny thing happened. This Congress forgot about the value of religious charity embodied in that legislation. Instead, forsaking the biblical injunction to forgive debts and deal generously with the poor, this Congress became a registered agent for the credit card industry.

How?

Well, it is because of the aggressive overreaching of the lending industry and a Congress willing to write into law any scrap of paper handed to it by large financial institutions that we have come to this point today. The decision in the Diagostino case relied solely on the text of the law Congress passed. It restricts a debtor in chapter 13, with current monthly income above the State median, to the narrow strictures of the means test which relies on what the IRS says a person needs to live on.

We debated the reliance on IRS guidelines to determine what a family needs to survive. We were all told not to worry, the IRS knows best and will provide all. Well, almost all.

It turns out that when you owe the IRS money, they don't want you making donations to your house of worship or to charity. And the IRS rule became a part of the Bankruptcy Code because Members of this House voted to give IRS bureaucrats that power.

We had managed to get a statutory allowance for tithing in the means test and in chapter 13, but the final language pushed through by the sponsors and the credit card industry did an end run around these provisions.

And that is how we got here. And I am glad that there is a will to fix it. This bill will allow chapter 13 debtors to tithe in their plans on the same basis as provided in the section 1325(b)(2)(A)(ii).

Keep in mind that while we are fixing the law for tithes and other charitable donations, basic problems in the law remain unchanged.

By wiping out the allowable expenses in chapter 13 for debtors with an income above the State median and replacing them with rigid IRS-based means tests, the new law still leaves families and small businesses at the tender mercies of the IRS. What else will we find was left out?

When the new law was being considered, Members were assured that the IRS guidelines would provide the right answer in all cases. And as we have discovered, that hasn't worked out as well as the credit card industry said it would.

This bill is supported by the United Way, the Red Cross, the National Council of Churches, Interfaith Alliance, the United Church of Christ, the National Baptist Churches USA, and the African Methodist Episcopal Church and others. I am pleased to urge all Members to support it.

But Members are fooling themselves if they think this is a discrete problem in a law that one proponent has described as perfect and that the sponsors told us was so well drafted that no amendments could even be considered.

The hubris has hurt real Americans and it will again.

Let's fix this mistake. It is the right thing to do, but we had better get used to doing it. The new Code is a disaster, the natural consequence of subcontracting work out of the Congress to lobbyists, which I am sure will be coming to an end very shortly.

I urge the passage of this legislation. I congratulate the chairman of the committee for bringing this matter to our attention.

□ 1530

Mr. CONYERS. Mr. Speaker, I yield back the balance of my time.

Mr. SENSENBRENNER. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, just very briefly, bringing this bill up in passing shows that the U.S. House of Representatives on a bipartisan basis has a much bigger heart than the Internal Revenue Service. Some people may have doubted that in the past. We are here to show them that they are wrong.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Wisconsin (Mr. SENSENBRENNER) that the House suspend the rules and pass the Senate bill, S. 4044.

The question was taken; and (two-thirds of those voting having responded in the affirmative) the rules were suspended and the Senate bill was passed.

A motion to reconsider was laid on the table.

VESSEL HULL DESIGN PROTECTION AMENDMENTS OF 2006

Mr. SENSENBRENNER. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 1785) to amend chapter 13 of title 17, United States Code (relating to the vessel hull design protection), to clarify the distinction between a hull and a deck, to provide factors for the determination of the protectability of a revised design, to provide guidance for assessments of substantial similarity, and for other purposes, as amended.

The Clerk read as follows:

S. 1785

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE I—VESSEL HULL DESIGN PROTECTION

SEC. 101. SHORT TITLE.

This title may be cited as the ''Vessel Hull Design Protection Amendments of 2006''.

SEC. 102. DESIGNS PROTECTED.

Section 1301(a) of title 17, United States Code, is amended by striking paragraph (2) and inserting the following:

''(2) VESSEL FEATURES.—The design of a vessel hull or deck, including a plug or mold, is subject to protection under this chapter, notwithstanding section 1302(4).''.

SEC. 103. DEFINITIONS.

Section 1301(b) of title 17, United States Code, is amended—

(1) in paragraph (2), by striking ''vessel hull, including a plug or mold,'' and inserting ''vessel hull or deck, including a plug or mold,'';

(2) by striking paragraph (4) and inserting the following:

''(4) A 'hull' is the exterior frame or body of a vessel, exclusive of the deck, superstructure, masts, sails, yards, rigging, hardware, fixtures, and other attachments.''; and

(3) by adding at the end the following:

''(7) A 'deck' is the horizontal surface of a vessel that covers the hull, including exterior cabin and cockpit surfaces, and exclusive of masts, sails, yards, rigging, hardware, fixtures, and other attachments.''.

TITLE II—INTELLECTUAL PROPERTY PROVISIONS

SEC. 201. SENSE OF CONGRESS RELATING TO BAYH-DOLE ACT.

(a) FINDINGS.—The Congress finds the following:

(1) Article I, section 8, clause 8, of the United States Constitution provides that Congress shall have the power ''[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries''.

(2) The 96th Congress enacted Public Law 96–517, entitled ''An Act to amend the patent and trademark laws'' (commonly known as the ''Bayh-Dole Act'', in honor of its two lead sponsors in the Senate, the Honorable Birch Bayh and the Honorable Bob Dole), in 1980.

(3) For 15 to 20 years before the enactment of the Bayh-Dole Act, Members of Congress considered, discussed, and deliberated on the proper resolution of issues implicated by the Act.

(4) Before the enactment of the Bayh-Dole Act, the United States was confronted by great economic uncertainty and presented with unprecedented new challenges from foreign industrial competition.

(5) Before 1980, only 5 percent of patents owned by the Federal Government were used by the private sector—a situation that resulted in the American people being denied the benefits of further development, disclosure, exploitation, and commercialization of the Government's patent portfolio.

(6) The Bayh-Dole Act established a ''single, uniform national policy designed to . . . encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such inventions to the point of commercial application'', and eliminated the 26 different Federal agency policies that had existed regarding the use of the results of federally funded research and development.

(7) The Bayh-Dole Act fundamentally changed the Federal Government's patent policies by enabling inventors or their employers to retain patent rights in inventions developed as part of federally funded research grants, thereby promoting licensing and the leveraging of contributions by the private sector towards applied research, and facilitating the transfer of technology from the laboratory bench to the marketplace.

(8) Examples of the tangible products and technologies that have resulted from the Bayh-Dole Act include, inter alia, an improved method for preserving organs for transplant, a lithography system to enable the manufacture of nano-scale devices, the development of new chemotherapeutic agents, the discovery of new therapies for the treatment of patients diagnosed with rheumatoid arthritis, and countless other advances in materials, electronics, energy, environmental protection, and information technologies.

(9) These new therapies, technologies, and inventions, which have resulted from the collaborative environment fostered by the Bayh-Dole Act, have directly contributed to the ability of medical researchers to discover and commercialize new treatments that alleviate patient suffering, enhance the ability of doctors to diagnose and treat disease, and target promising new medical research.

(10) The Bayh-Dole Act has stimulated two of the major contemporary scientific trends of the last quarter century—the development of the biotechnology and information communications industries—and the Act is poised to continue playing a central role in new fields of innovative activities, including nanotechnology.

(11) The Bayh-Dole Act has resulted in benefitting taxpayers by generating millions of dollars in annual licensing royalties for universities and nonprofit institutions—revenues that are reinvested in furtherance of additional research and education programs.

(12) The incentives provided under the Act and the exchange of technology and research between and among the research community, small businesses, and industry, have resulted in new cooperative ventures and the emergence of sophisticated high-technology businesses, which provide a major catalyst for innovation and entrepreneurial activity.

(13) More than 4,000 new companies have been created to develop and market academic research and development since 1980, and it is estimated that nearly 2300 of these companies were still in operation at the end of fiscal year 2003.

(14) Lita Nelsen, director of the Technology Licensing Office at the Massachusetts Institute of Technology, has described the Bayh-Dole Act as ''one of the most successful pieces of economic development and job-creation legislation in recent history''.

(15) The Bayh-Dole Act was described in a 2002 article in The Economist (US) as ''[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century. . . . More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance''.

(16) The Government Accountability Office (GAO) found that university administrators and small business representatives considered the Bayh-Dole Act to have had ''a significant impact on their research and innovation efforts''.

(17) A study of business executives found that 9 out of 10 identified the Bayh-Dole Act as an ''important factor'' in decisions to fund research and development in academia.

(18) Howard Bremer, who served as patent counsel to the Wisconsin Alumni Research Foundation from 1960 to 1988, once observed that, ''[o]ne important factor . . . is that the success was achieved without cost to the taxpayer. In other words, no separate appropriation of government funds was needed to establish or manage the effort''.

(19) A 1998 GAO study found that the law had a positive impact on all involved and that the increased commercialization of federally funded research that resulted from implementation of the Act had positively affected both the Federal Government and the American people.

(20) The President's Council of Advisors on Science and Technology reported to the President in May 2003 that the Act ''dramatically improved the nation's ability to move ideas from research and development to the marketplace and into commerce'' and that the system put in place for transferring technology from nonprofit institutions, which includes universities and Government laboratories, to the private sector has worked well.

(21) The Bayh-Dole Act states, ''[i]t is the policy and objective of the Congress to promote the utilization of inventions arising from federally-supported research or development; . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally-supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions''.

(22) The Congress finds that the policies and objectives of the Bayh-Dole Act have been achieved and that the patent law has played a critical role in stimulating technological advances and disclosing useful technical information to the public.

(23) The Congress finds that federally-funded research at universities and Government laboratories and the partnerships between such nonprofit institutions and the private sector play a critical role in developing the technologies that allow the United States to lead the world in innovation.

(24) The Bayh-Dole Act and its subsequent amendments, which include the Trademark Clarification Act of 1984 (Public Law 98-620), have played a vital role in enabling the United States to become renowned as the world leader in scientific research, innovation, ingenuity, and collaborative research that involves institutions of higher education and the private sector.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) the Bayh-Dole Act (Public Law 96–517) has made substantial contributions to the advancement of scientific and technological knowledge, fostered dramatic improvements in public health and safety, strengthened the higher education system in the United States, served as a catalyst for the development of new domestic industries that have created tens of thousands of new jobs for American citizens, strengthened States and local communities across the country, and benefitted the economic and trade policies of the United States; and

(2) it is appropriate that the Congress reaffirm its commitment to the policies and objectives of the Bayh-Dole Act by acknowledging its contributions and commemorating the silver anniversary of its enactment.

SEC. 202. FILING OF APPLICATIONS FOR EXTENSIONS OF A PATENT TERM.

(a) FINDINGS.—The Congress finds the following:

(1) The Congress historically has provided vigorous support for innovation in the useful arts by establishing a system of patent protection for products and processes.

(2) Through section 156 of title 35, United States Code, the Congress sought to promote the development of innovative drugs by granting patent term restoration to companies to recover a portion of the patent term for such drugs that was consumed during the approval process conducted by the Food and Drug Administration.

(3) Consistent with the historic purpose of promoting innovation, patent legislation, and subsequent rules promulgated by the United States Patent and Trademark Office (PTO), have routinely given the PTO wide discretion to excuse late filings and other mistakes that might otherwise result in the forfeiture of underlying patent rights.

(4) Contrary to this routine practice, however, under section 156 of title 35, United States Code, the PTO has no discretion to excuse a filing that is even one day late.

(5) In order to be consistent with the intent of protecting patent rights and promoting further innovation, the PTO should be granted limited, circumscribed discretion to consider patent term restoration applications filed in an untimely manner.

(b) FILING OF APPLICATIONS.—

(1) IN GENERAL.—Section 156 of title 35, United States Code, is amended by adding at the end the following new subsection:

''(i) UNINTENTIONAL DELAY.—The Director may accept an application under this section that is filed not later than 5 days after the expiration of the 60-day period provided in subsection (d)(1) if the applicant files a petition showing, to the satisfaction of the Director, that the delay in filing the application was unintentional. Such petition must be filed with the application in the case of an application filed on or after the date of the enactment of this subsection and must be filed not later than 5 days after such date of

enactment in the case of an application which, on such date of enactment, is pending, is the subject of a request for reconsideration of a denial of a patent term extension under this section, or has been denied a patent term extension under this section in a case in which the period for seeking reconsideration of such denial has not yet expired. The Director shall make a determination on a petition under this subsection not later than 30 days after the date on which the petition is received. If no determination has been made on the petition within that 30-day period, the petition shall be deemed to be denied.''.

(2) REVIVAL FEES.—Section 41(a)(7) of title 35, United States Code, is amended—

(A) by striking ''or for an'' and inserting ''for an''; and

(B) by inserting after ''reexamination proceeding,'' the following: ''or for an unintentionally delayed application for patent term extension,''.

(3) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act, and shall apply to any application for patent term extension under section 156 of title 35, United States Code, which—

(A) is filed on or after the date of the enactment of this Act; or

(B) on such date of enactment—

(i) is pending;

(ii) is the subject of a request for reconsideration of a denial of a patent term extension under section 156; or

(iii) has been denied a patent term extension under such section 156 in a case in which the period for seeking reconsideration of such denial has not yet expired.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Wisconsin (Mr. SENSENBRENNER) and the gentleman from Michigan (Mr. CONYERS) each will control 20 minutes.

The Chair recognizes the gentleman from Wisconsin.

GENERAL LEAVE

Mr. SENSENBRENNER. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and include extraneous material on S. 1785 currently under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Wisconsin?

There was no objection.

Mr. SENSENBRENNER. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of S. 1785, a bill to amend the Vessel Hull Design Protection Act. The version before us is the manager's amendment to the bill. In addition to the vessel hull design amendments, S. 1785 includes the text of three other intellectual property bills that have been the focus of considerable bipartisan discussion and deliberation. These bills are not controversial and therefore have been included as a part of the manager's amendment.

First, S. 1785 amends the Vessel Hull Design Protection Act by requiring courts to examine the statutorily protected components of a vessel, the hull as well as the deck, separately when determining whether a third party has infringed on a design.

This change responds to a Fifth Circuit Court case which, if allowed to stand, will render the statute meaningless, thereby encouraging knock-off artists to sell boats with inferior-designed hulls to consumers. The Judiciary Subcommittee on the Courts, the Internet, and Intellectual Property reported this bill favorably to the full committee on March 1, 2006.

Second, S. 1785 includes the text of House Concurrent Resolution 319, which commemorates the Bayh-Dole Act on its 25th anniversary. This is the law that enables inventors to retain their property interest in patented products that are subsidized by Federal financing. The concurrent resolution was unanimously approved by the Judiciary Committee earlier this year.

Third, S. 1785 includes the text of H.R. 5120, a bill that amends title 35, United States Code, to conform certain filing provisions within the Patent and Trademark Office. This legislation allows the director of the PTO to accept a pharmaceutical patent extension request for not later than 5 days after the current statutory deadline, which is 60 days from the date that the Food and Drug Administration approves the drug for use.

The applicant must prove to the director's satisfaction that the delay in filing was unintentional. In any event, the director retains the discretion to grant or to deny an extension. It is not automatic. The Subcommittee on Courts, the Internet, and Intellectual Property conducted a hearing on H.R. 5120 on September 14.

Finally, S. 1785 includes the text of H.R. 2955, the Intellectual Property Jurisdiction Clarification Act. This measure responds to a recent court case by reaffirming the plenary authority of the Federal Circuit to hear all patent appeals, which was the clear intent of Congress since the circuit's creation in 1982. This bill was reported by the Judiciary Committee on April 5 of this year by a voice vote.

Mr. Speaker, S. 1785 incorporates timely bipartisan legislation to enhance public safety, commemorate the Bayh-Dole Act and make other needed clarifications and improvements to U.S. intellectual property law.

I urge my colleagues to support the legislation and send it to the other body to ensure its timely consideration and passage.

Mr. Speaker, I reserve the balance of my time.

Mr. CONYERS. Mr. Speaker, I am pleased to yield myself as much time as I may consume.

Mr. Speaker, I rise in support of the legislation consisting of these intellectual property bills that have been very fully and accurately described by our Chairman SENSENBRENNER.

I rise in support of this legislation, which consists of three intellectual property bllls.

VESSEL HULL PROTECTION

First, the bill amends the Vessel Hull Design Protection Act by requiring courts to examine the copyright protected components of a vessel—the hull as well as the deck—separately when determining whether a third party has infringed a design. This change responds to a 5th Circuit case that would render the statute meaningless, thereby encouraging knock-off artists to sell boats with inferior designed hulls to consumers.

BAYH-DOLE RESOLUTION

Section 201 of the package consists of H. Con. Res. 319, a resolution that commemorates the Bayh-Dole Act on its 25th anniversary. The Bayh-Dole Act, named after Sen. Birch Bayh (D–IN) and Sen. Bob Dole (R–KS), is the law that enables inventors to retain their property interests in patented products that are subsidized by federal funding. It is fitting that we again have senators named BAYH and DOLE in the Senate. The Committee reported this bill favorably in April.

PATENT TERM EXTENSION APPLICATIONS

Section 202 consists of the text of H.R. 5120. It permits the Director of the Patent and Trademark Office to accept late-filed requests for patent term extension. The applicant must prove that the delay in filing was unintentional. In addition, the Director retains the discretion to grant an extension and is not required to issue one.

I urge my colleagues to vote "yes" on this legislation.

Mr. Speaker, I am now pleased to recognize the gentleman from Oregon (Mr. WU), from the Science Committee, for as much time as he may consume.

Mr. WU. I thank the ranking member, and I thank the chairman.

Mr. Speaker, I rise in support of section 201 of S. 1785 and, in particular, its well-deserved commendation of the Bayh-Dole Act of 1980. This act, and its 1984 amendments, were cited by The Economist in December 14, 2002, as possibly the most inspired piece of legislation to be enacted in the past half century.

The reasons are apparent if one looks at the revolutionary changes that began with Bayh-Dole. In 1980, perhaps half a dozen universities were strongly committed to commercialization of university research results. Today, it is hard to find a university that does not have a tech transfer licensing program to take advantage of this legislation.

In the 1970s, we were struggling to keep up with international competition. Bayh-Dole made research universities a major tool in our tool box as an antidote to that decline.

Initially, by keeping the intellectual property rights to the ideas they generated, universities were able to bring in revenues, share with professor inventors, as industry began to commercialize the fruits of university research. Some of the inventions in biotechnology and computer software and hardware by institutions such as the Oregon Health and Science University, the University of Oregon and Stanford University, were listed by AUTM, the Association of University Technology Managers, in the top 100 inventions that changed American life.

As success has mounted and more and more university professors thought about the commercial implications of their work, new opportunities opened

up for professors. This led to university research centers, research parks and technology transfer offices, adding many more services as professors began startup companies. Bayh-Dole is a major reason why both research universities and small high-tech companies with university roots are such major drivers of today's American economy.

None of this would have been possible without the cooperation of the Committee on the Judiciary and its Courts Subcommittee and the Committee on Science and its Technology Subcommittee, where I am proud to serve as subcommittee ranking Democratic member.

It is fitting that Chairman SENSENBRENNER, who was on both committees at the time of the 1984 amendments, and who went on to serve as chairman of both full committees, has chosen to bring this commemoration forward in a bipartisan manner that involves both committees.

I thank both gentlemen. I thank him for his continued leadership, and I look forward to working with him, not only to commend Bayh-Dole today, but perhaps also to update and improve in the coming years after a successful quarter century run.

Mr. SENSENBRENNER. Mr. Speaker, I yield 3 minutes to the gentleman from Tennessee (Mr. JENKINS).

Mr. JENKINS. Thank you, Chairman SENSENBRENNER, for yielding this time.

Mr. Speaker, H.R. 5120, which is incorporated into section 202 of S. 1785 has drawn bipartisan sponsorship from 23 of our colleagues in the House. I introduced this measure because I believe it is both good patent policy and sound health care policy.

It corrects an inequity in the patent law and will encourage important innovation in medical research, precisely the purpose that Congress sought to accomplish in enacting the Hatch-Waxman Act. In the patenting process, there are several examples of relief that are available for late filings, late payments and deficient filings.

By enacting section 202 of S. 1785, we are continuing to promote the basic purpose of Hatch-Waxman, and we are strengthening Hatch-Waxman. It is important to do this so that our Nation will continue to lead the way in medical research, and so that patients will not be denied promising new innovative developments.

Mr. Speaker, I include for the RECORD letters from medical practitioners and consumer groups from across this country supporting this legislation. Included are letters from the Cleveland Clinic Foundation Heart Center, the Emory University Healthcare Heart Center, and the University of California Los Angeles Medical Center Cardiology Section. Their credentials and their views are impressive. They emphasize the health care advantages of this measure, particularly its effect on opening up new advantageous avenues of medical research to prevent and treat stroke.

THE CARLYLE FRASER HEART CENTER
AT CRAWFORD LONG HOSPITAL,
Athens, GA, June 15, 2006.

Congressman JOHN LEWIS,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE LEWIS: I received a phone call today from Clive Meanwell, Chief Executive Officer of The Medicines Company, regarding H.R. 5120, relating to the patent restoration provisions of the Hatch-Waxman law. I am the Director of Interventional Cardiology at Emory Crawford Long Hospital and have been on the faculty of Emory University School of Medicine for thirteen years. I am also the President of the Greater Atlanta Division of the American Heart Association (AHA), and a medical reporter for FOX–5 television. The major focus of my profession is the care of patients with advanced and complex cardiovascular disease, particularly those undergoing interventional procedures (commonly known as stents) of the arteries of their heart and elsewhere in the body.

I am writing in support of H.R. 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. Angiomax is a critically important product which is used in the overwhelming majority (thousands) of the interventional procedures at Emory. Angiomax is an important therapy because it provides safe, effective, and cost-effective anti coagulation during interventional procedures. In addition, several Emory physicians have performed extensive research on Angiomax. Emory was one of the leading U.S. centers in a recent trial studying this product. I am perhaps one of the Nation's leading experts and researchers in this area and have lectured internationally and published extensively in this area. Within the last month, we submitted approximately twenty individual research abstracts on Angiomax to the American Heart Association and Transcatheter Cardiovascular Therapeutics national meetings. Our research shows that Angiomax provides equal efficacy to other drugs, costs less, is easier to use, and causes less risk of bleeding complications. Bleeding complications have been shown to increase mortality and are particularly common in patients who are: elderly, female, African-American, and those with kidney disease, anemia, and high blood pressure. I have attached two of our abstracts highlighting the consequences of bleeding complications. These types of patients make up the majority of the patients at our institution. Better outcomes and a reduction in healthcare costs with Angiomax is what we want for the patients of our community.

But that is only part of the story. Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the Nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year—one every 45 seconds; over 165,000 die and many thousand more are disabled for life. I know that you are aware that Georgia is part of the high-risk ''stroke belt''. In my capacity with the AHA, one of our major initiatives is reducing the risk of stroke. Unfortunately, the blood thinning and clot-busting agents currently utilized to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer bleeding side effects. But the very costly and time-consuming clinical trials (which Emory will likely be involved with) which will be needed to explore this and other promising new uses (such as patients undergoing open-heart surgery) will not be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that H.R. 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I would be happy to discuss this matter further with you at your convenience.

Very truly yours,

STEVEN V. MANOUKIAN, M.D.,
Director, Interventional Cardiology, Emory Crawford Long Hospital, Emory University School of Medicine.

THE 60 PLUS ASSOCIATION,
Arlington, VA, September 13, 2006.

Hon. F. JAMES SENSENBRENNER,
Chairman, House Committee on the Judiciary,
Washington, DC.

DEAR CHAIRMAN SENSENBRENNER: On behalf of the members of the 60 Plus Association, I am writing to inform you of our support for H.R. 5120, a bill to Amend Title 35, United States Code, To Conform Certain Filing Provisions within the Patent and Trademark Office. This important legislation would amend the Hatch-Waxman Act, correcting a disconcerting irregularity in the Act that hinders drug innovation and life-saving research.

Patent law is designed to encourage innovation and advancement. The Hatch-Waxman Act supports this purpose in a variety of ways including not penalizing the owner of a drug patent for the time it has to wait for FDA approval. However, the Act's rigid 60-day deadline for filing an application for patent term restoration with the Patent and Trademark Office (PTO) undermines these objectives, as it does not allow the PTO any discretion to excuse minor mistakes. H.R. 5120 would provide the PTO with this vital discretionary authority to accept an application for patent term restoration filed within 5 days after the current deadline if the PTO finds that the filing delay was unintentional.

As you are probably aware, coronary artery disease kills 500,000 Americans each year—earning the dubious distinction of being the leading cause of death in America for both men and women. And stroke is the Nation's number one cause of disability, affecting 700,000 Americans each year. Angiomax is a drug which has already been shown safe and effective in angioplasties and has shown initial promise for patients with coronary artery disease or stroke. Unfortunately, because of a minor administrative error that caused its manufacturer's application to be filed one day late, Angiomax may never reach these cardiac and stroke patients, even though it had earned the right to patent restoration.

H.R. 5120 would prevent such destructive and unnecessary results, now and in the future. A similar clerical error has already happened to two other companies, who also missed the filing deadline by one day. And, human error being what it is, it is virtually certain to happen to other companies in the future.

The 60 Plus Association urges the House Judiciary Committee to support this important, bipartisan legislation that will benefit millions of seriously ill patents, many of whom are 60 years of age and older. It is incredibly unfortunate that years of patent protection on drugs are forfeited due to a

minor clerical error and, as a result, the benefits of further research and development of critical drugs are often lost.

The 60 Plus Association appreciates your leadership on this issue. We hope you will consider these points and support this vital legislation—legislation that will directly benefit the aging population. If you have any questions or concerns, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

JIM MARTIN,
President, 60 Plus Association.

RETIRESAFE,
September 13, 2006.

Hon. F. JAMES SENSENBRENNER,
Chairman, House Committee on the Judiciary, Washington, DC.

DEAR CHAIRMAN SENSENBRENNER: On behalf of the almost 400,000 senior citizens represented by RetireSafe, I am writing to inform you of our support of H.R. 5120, legislation that would correct a troubling anomaly in the patent law that can hinder innovation and stymie life-saving research. Currently, the Hatch Waxman Act allows the owner of a drug patent to obtain time restored to its patent to make up for time lost while awaiting FDA approval. H.R. 5120 would permit the Patent and Trademark Office to accept an application within 5 days of the deadline if the PTO determines the filing delay was unintentional.

RetireSafe urges the House Judiciary Committee to support this much needed legislation that can benefit millions of seriously ill patents. It's unfortunate, but when years of patent protection on a drug are forfeited due to a minor clerical error, the benefits of further research and development of critical drugs is often lost. Ironically, there are more than 30 patent laws and regulations on the books giving the PTO the discretion to accept minor application errors and late filings, but not under Hatch-Waxman. We believe such rigid rules undermine the intent and basic purposes of the patent law.

Furthermore, there are absolutely no downsides to fixing this problem. The bill would not upset the balance of Hatch-Waxman; it would simply avoid a premature cutoff of earned patent rights due to minor clerical error. Generic manufactures will also still have the same right they now enjoy to file an application to bring out a new drug, and this right would still be keyed to the date FDA approves the patent owner's drug use.

For instance, take the case of the drug Angiomax, made by a small drug company, which had earned the right to patent restoration but missed the filing deadline by one day. Research into promising new applications of Angiomax for cardiac and stroke patients—applications which are critical to older Americans—will be cut short if this legislation is not passed. If Angiomax loses its patent protection prematurely, this critical research opportunity will be lost entirely as it will never be conducted by generic manufacturers. The end result will mean that 13 million Americans including the millions of seniors with coronary artery disease will never benefit from this potentially life-saving drug.

Angiomax is just one example of a drug that has faced this filing deadline issue. Two other companies have missed the Hatch-Waxman filing deadline by one day and others will doubtless make minor filing errors in the future. Cardiac and stroke patients will clearly benefit from this bill. H.R. 5120 is good public policy that will help save lives and provide a better quality of life for seriously ill patients, and it should be enacted immediately.

In short, H.R. 5120 does not give anything to patent owners that the Hatch-Waxman law did not intend to give them and does not take anything away from the generic manufactures that the Hatch-Waxman law intended to provide. It merely gives PTO the discretion to consider whether or not to accept an application for patent term restoration after hearing all the facts.

I urge you and your committee to support H.R. 5120 and help millions of seniors in this country who are currently suffering or at risk for coronary artery disease and need innovative life-saving medications. It is my hope you will agree that H.R. 5120 is good public policy with an overriding public health benefit.

Sincerely,

MICHELLE PLASARI,
RetireSafe.

FREEDOMWORKS,
Washington, DC, September 13, 2006.

Hon. F. JAMES SENSENBRENNER, Jr.,
Chairman, Committee on the Judiciary, House of Representatives, Washington, DC.

Hon. JOHN CONYERS, Jr.,
Ranking Member, Committee on the Judiciary, Washington, DC.

DEAR CHAIRMAN SENSENBRENNER AND RANKING MEMBER CONYERS, on behalf of the 800,000 members of Freedom Works, I am writing to urge your support for H.R. 5120, a bill that would address a concern that has arisen in patent law and provide an environment that facilitates innovation and continued development of products that are beneficial to potentially millions of Americans. Freedom Works has a long history of involvement with issues arising from the drug approval process, promoting policies that eliminate unnecessary delays that limit consumer access to important new therapies. In addition, Freedom Works believes that at times the patent process may be abused and generics provide an important source of competition that generates substantial benefits to consumers. This legislation, however, is not an abuse of the system; it is an adjustment to the process that will ensure continued research and development. This issue also highlights the burden imposed by the drug approval process and I would urge Congress to also consider reforms in this area as well to ensure Americans have the access to the best care possible.

Briefly, H.R. 5120 would grant the U.S. Patent Office the discretion to consider an application for patent term restoration that unintentionally has been filed late, but within five days of the expiration of the 60-day filing period established in the Hatch-Waxman Act (see 35 U.S.C. Section 156(d)(1)). The U.S. Patent Office has the discretion to accept late-filed submissions in a variety of patent and trademark proceedings, but it does not in instances of patent term restoration filings. H.R. 5120 would correct this anomaly.

Under the Hatch-Waxman Act, patent term restoration is an inducement for innovators and firms to undertake risky, time-consuming, and costly drug development and the FDA approval processes. Without patent term restoration, incentives for drug innovation are diminished and consumers would bear the costs as fewer resources are devoted to important lifesaving drug therapies.

As an example, the Medicines Company failed to receive patent restoration because its filing was unintentionally filed one day late. The firm was in the process of conducting important additional research on Angiomax, a drug initially approved as a blood thinning agent. New research, however, suggests that Angiomax may be beneficial for use in the prevention and treatment of stroke, which is the leading cause of disability and third leading cause of death in the United States. Unfortunately, without patent restoration, the ability to conduct the additional research and commit to the costly approval process are eliminated, leaving consumers with fewer choices for critical health care decisions.

Unlike other areas of patent law, the inflexible filing deadline is clearly draconian. The Hatch-Waxman act provides incentives to invest in the costly and time-consuming drug approval process, yet the inflexibility built into the current law can destroy those incentives and have a disproportionate impact on the process, and reduce opportunities for innovation. H.R. 5120 brings this application of patent law more in line with the broader process for patent and trademark proceedings. Given the importance of innovation in the field of health care, and the potential impact on the lives of Americans, I urge you to support this important legislation.

Sincerely,

MATT KIBBE,
President and CEO.

CENTER FOR INDIVIDUAL FREEDOM,
Alexandria, VA, September 12, 2006.

Hon. F. JAMES SENSENBRENNER, Jr.,
Chairman, House Judiciary Committee, Washington, DC.

Congressman JOHN CONYERS, Jr.,
Ranking Member, House Judiciary Committee, Washington, DC.

DEAR CONGRESSMAN SENSENBRENNER AND CONGRESSMAN CONYERS: On behalf of the Center for Individual Freedom and its more than 250,000 supporters and activists nationwide, I am writing to urge you to support H.R. 5120. This bill grants the Patent and Trade Office Director the discretion, where fair and appropriate, to accept slightly overdue patent-term restoration applications under the Hatch-Waxman law.

Under current law, an application unintentionally filed even one day late must be denied—the Director possesses absolutely no discretion whatsoever. Such a rigid command creates unfair outcomes, and arbitrarily jeopardizes enormously valuable property rights.

Throughout other realms of business, legal, and personal life, equitable grace periods exist. For example, other federal agencies such as the Internal Revenue Service possess discretion to accept slightly overdue submissions. If even the ''Tax Man'' can have a heart, the Patent and Trademark Office should also be allowed similar discretion.

It is also important to put H.R. 5120 into perspective: the bottom line is that a company should not have to pay the price of millions or even billions of dollars in revenue due to a simple and unintentional clerical error. Companies invest billions of dollars in product research and development, and recouping those investments through patent protection is what allows our innovative economy to thrive.

Moreover, other patent laws and regulations allow the Patent and Trade Office discretion to excuse minor mistakes, such as filing documents or making payments. Thus the current Hatch-Waxman deadline provision stands as an anomaly by prohibiting any type of discretion. In our view, this anomaly should be fixed, and H.R. 5120 does just that.

If an individual unintentionally pays their mortgage payment one day late, does the bank seize their home? No. If property taxes are paid one day late due to a bank disbursement error, does the government automatically seize your property? Obviously not. Should a different standard apply to a company whose very existence depends upon a patent that they hold?

Opponents of this rational legislation claim that it would somehow benefit one particular company, but that is incorrect. Rather, any company that can prove that its slight delay was unintentional would be treated more fairly. This is simply good public policy.

Indeed, the only beneficiaries of perpetuating the current regulations are generic companies who stand to gain an unfair windfall by pouncing whenever a patent owner accidentally files a few days late. Perpetuating such inequitable windfalls for generic companies is an inappropriate public policy result. Maintaining the Hatch-Waxman mandate as-is will lead to the further loss of highly valuable patent rights for no good reason. In contrast, fixing it through H.R. 5120 will help all innovators, both present and future.

Further, H.R. 5120 does not give the patent holder a ''carte blanche, no questions asked'' grace period. It does not allow for indefinite patents, nor does it imply continued protections due to intentional negligence. Rather, it allows a five-day grace period for a patent restoration filing that was unintentionally delayed. Five days.

Finally, Congress routinely revisits statutes in order to fix loopholes and anomalies. Very simply, mistakes happen, as does the law of unintended consequences. In the case of Hatch-Waxman, allowing a simple five-day grace period will not undermine or compromise the growth of the generics market in the United States. Rather, H.R. 5120 will merely align patent restoration filing rules with the other discretions enjoyed by the Patent and Trademark Office.

Accordingly, the Center for Individual Freedom urges you and all members of the Judiciary Committee to pass H.R. 5120, allowing it full consideration by the U.S. House of Representatives. Fairness and equity demands it, and we will monitor members' votes on this critical matter and communicate them to our constituency.

Thank you very much for your time and consideration.

Sincerely,

TIMOTHY H. LEE,
Director of Legal and Public Affairs.

THE CLEVELAND CLINIC
FOUNDATION HEART CENTER,
Cleveland, OH, April 24, 2006.

Congresswoman STEPHANIE TUBBS JONES,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE TUBBS JONES: I understand that you are considering a bill, HR 5120, related to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at the Cleveland Clinic. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of H.R. 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Angiomax and have been involved In the study of Angiomax in acute care cardiovascular procedures, including heart attack and angina. Angiomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save the health care system money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke, but more studies are needed. Stroke is the nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year—one every 45 seconds; over 165,000 die and many thousands more are disabled for life, Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that H.R. 5120 be enacted so that research on Angiomax in the prevention and treatment of strokes is undertaken to evaluate the drug in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

DEEPAK L. BHATT,
Associate Director, Cleveland Clinic Cardiovascular Coordinating Center, Staff, Cardiac, Peripheral, and Carotid Intervention, Associate Professor of Medicine, Department of Cardiovascular Medicine, Cleveland Clinic Foundation.

DEPARTMENT OF MEDICINE, UCLA
SCHOOL OF MEDICINE, CENTER FOR
THE HEALTH SCIENCES,
Los Angeles, CA September 6, 2006.

Congresswoman NANCY PELOSI,
House of Representatives,
Washington, DC.

DEAR CONGRESSWOMAN: I understand that the Subcommittee on Courts, the Internet and Intellectual Property of the Judiciary Committee of the House of Representatives is considering a bill, H.R. 5120, relating to the patent restoration provisions of the Hatch-Waxman law. I am an interventional cardiologist practicing at The UCLA Medical Center and the Greater Los Angeles Veterans Administration Medical Center. I engage in the clinical care of patients with cardiovascular disease as well as in clinical research related to this complex and unique group of patients.

I am writing in support of H.R. 5120 because I understand that, if it passes, the anticoagulant drug Angiomax may become eligible for patent term restoration. This would allow for further investment in clinical development. I use Angiomax and have been involved in the study of Angiomax in acute care cardiovascular procedures. Angiomax is an important therapy that provides safe and effective anticoagulation in interventional procedures with less bleeding than other treatments. These advantages also save money by reducing bleeding and providing single drug therapy versus combination drug therapy.

Patent term restoration for Angiomax is important because preliminary experience suggests that Angiomax may be useful in preventing and treating stroke but more studies are needed. Stroke is the Nation's number one cause of disability and third leading cause of death. Over 700,000 Americans suffer strokes each year—one every 45 seconds; over 165,000 die and many thousands more are disabled for life. Unfortunately, the blood thinning and clot-busting agents now available to treat stroke patients can cause dangerous side effects, including intracranial bleeds (as was seen so vividly with Israeli Prime Minister Sharon). Angiomax may be useful in the prevention and treatment of strokes with fewer side effects. But the very costly and time-consuming clinical trials needed to explore this promising new use won't be feasible unless patent term restoration under the Hatch-Waxman Act is available to the drug's developer.

It is vital that H.R. 5120 be enacted so that research in stroke is undertaken to evaluate the use of Angiomax in the treatment and prevention of this debilitating disease. I am available to discuss this matter further with you at your convenience.

Very truly yours,

RAMIN EBRAHIMI,
Associate Clinical Professor, University of California Los Angeles, Director, Cardiac Catheterization Laboratory, Greater Los Angeles VA Medical Center, Assistant Director, Nuclear Cardiology, Greater Los Angeles VA Medical Center.

Section 202 is narrowly tailored legislation. It simply confers discretion on the Patent Office to consider an unintentionally late-filed patent term restoration application submitted to the Patent Office within 5 days of the 60-day deadline in current law. It does not confer any substantive rights on any applicant, but merely allows the applicant to present the facts surrounding the late filing to the Patent Office. The director of the Patent Office then has 30 days to rule on the petition.

Honest mistakes should not cause irreparable hardship for innovators or patients. A few days unintentional late filing mistake at the Patent Office should not be cause for blocking promising medical research that could lead to important health care advantages.

Mr. Speaker, I appreciate all the efforts the committee has invested in bringing this legislation to the floor, and I hope that we can now proceed with the enactment of S. 1758.

Mr. CONYERS. Mr. Speaker, I yield back the balance of my time.

Mr. SENSENBRENNER. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Wisconsin (Mr. SENSENBRENNER) that the House suspend the rules and pass the Senate bill, S. 1785, as amended.

The question was taken; and (two-thirds of those voting having responded in the affirmative) the rules were suspended and the Senate bill, as amended, was passed.

The title of the Senate bill was amended so as to read: ''An Act to make certain improvements relating to intellectual property, and for other purposes.''.

A motion to reconsider was laid on the table.

HONORING THE LIFE OF RUTH BROWN

Mr. SENSENBRENNER. Mr. Speaker, I move to suspend the rules and agree to the resolution (H. Res. 1090) honoring the life of Ruth Brown and her copyright royalty reform efforts on behalf of rhythm and blues recording artists.

The Clerk read as follows:

H. RES. 1090

Whereas Ruth Brown passed away on November 17, 2006;